

Nuclear Regulatory Commission

§ 72.144

the Commission, docket number, and date of Commission approval.

[53 FR 31658, Aug. 19, 1988, as amended at 65 FR 50617, Aug. 21, 2000; 66 FR 51843, Oct. 11, 2001]

§ 72.142 Quality assurance organization.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee and certificate holder may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee and the certificate holder shall retain responsibility for the program. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components which are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are—

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

(c) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these considerations are opposed to safety considerations, are provided. Because of the many variables involved, such as

the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

§ 72.144 Quality assurance program.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this subpart. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with these procedures throughout the period during which the ISFSI or MRS is licensed or the spent fuel storage cask is certified. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall identify the structures, systems, and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC, through their quality assurance program(s), shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each ISFSI, MRS, or spent fuel storage cask. The licensee, applicant for a license, certificate holder, and applicant for a

CoC shall ensure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools and skills to attain the required quality and the need for verification of quality by inspection and test.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall base the requirements and procedures of their quality assurance program(s) on the following considerations concerning the complexity and proposed use of the structures, systems, or components:

(1) The impact of malfunction or failure of the item on safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(d) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

(e) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must regularly review the status and adequacy of that part of the quality assurance program which they are executing.

§ 72.146 Design control.

(a) The licensee, applicant for a license, certificate holder, and applicant

for a CoC shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license or CoC application for those structures, systems, and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee and certificate holder shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee and certificate holder shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress,